American Health Information Management Association®

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June 29, 2012

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: **Governance RFI**
Herbert Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Dear Principal Deputy Muntz:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office of the National Coordinator for Health Information Technology's request for information regarding the Nationwide Health Information Network: Conditions for Trusted Exchange, as published in the May 15, 2012 *Federal Register*.

AHIMA is a professional association representing more than 64,000 health information management (HIM) professionals who work throughout the healthcare industry. HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, protecting, validating the integrity of, reporting, and releasing data vital for patient care, while making it accessible to patients, healthcare providers, authorized requestors, and appropriate researchers when it is needed most. AHIMA members are deeply involved in the development, planning, implementation and management of electronic health records, in addition to the analysis and reporting of healthcare data for secondary use.

Our detailed comments and recommendations on the RFI are found below.

Question	Comments
Establishing a Governance Mechanism	
Question 1: Would these categories comprehensively reflect the types of CTEs needed to govern the nationwide health information network? If not, what other categories should we consider?	In addition to the proposed categories of CTEs, AHIMA recommends the development of CTEs that would guide and ensure HIE information stewardship and integrity. We believe focusing on information stewardship and integrity is crucial to data accuracy, as information persists throughout the HIE, it is imperative that the information be accurate. We believe that CTEs should be modeled after many of the elements of the Data Use and Reciprocal Support Agreement (DURSA) information trust agreement that require the receiving Party to hold all Confidential Information in trust and confidence, unless such use or disclosure is permitted by the terms of the agreement. We also support the need for conditions of trusted exchange that address the governance of financial aspects.
Question 2: What kind of governance approach would best produce a trusted, secure, and interoperable electronic exchange nationwide?	AHIMA suggests creating an organized governance entity (outside of the Office of the National Coordinator (ONC) Health Information Technology Policy and Standards Committees) that includes active participation from stakeholders such as vendors, healthcare plans, healthcare providers, and consumers. This governance process needs to be transparent and inclusive during NwHIN development. The creation of mechanisms for ensuring robust communications and evaluation of input are critical to the mission of the governance entity.
Question 3: How urgent is the need for a nationwide governance approach for electronic health information exchange? Conversely, please indicate if you believe	Health Information Exchange (HIE) has moved beyond the planning stages with HIEs throughout the country achieving the ability to sustain them. If a nationwide governance approach for electronic health information exchange is not introduced quickly, a considerable amount of additional time and expense will be required to rework the

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that it is untimely for a nationwide approach to be developed and why.	policies and procedures of the early adopters to achieve compliance with HIE governance standards. AHIMA strongly supports the development of a nationwide governance approach for electronic health information exchange. There have been several industry publications validating the rapid rate of HIE adoption: According to a recent KLAS survey, the number of active private HIEs has tripled from 52 in 2009 to 161 in 2010.[i] The eHealth Initiative (eHI) identified 255 known health exchange initiatives in 2011, up from 234 in 2010. Of the 255 known HIEs, 196 were surveyed, 24 (12%) currently reported being self-sustaining. Many more HIEs are rapidly approaching the status of full sustainability.[ii] A 2011 CapSite survey of 340 hospitals found that 74 percent plan to purchase new HIE solutions in the near future. That share is nearly double from when CapSite surveyed hospitals in 2009. When asked which HIE they were considering, respondents identified a mix of private and state HIEs.[iii]
Question 6: How could we ensure alignment between the governance mechanism and existing State governance approaches?	The Electronic Healthcare Network Accreditation Commission (EHNAC) – Health Information Exchange Accreditation Program (HIEAP) focuses on technical performance, business processes, and resource management. This serves as a lever by which alignment of governance approaches among states can occur. According to the EHNAC website, their accreditation program "organizations will discover ways to improve efficiency, elevate quality of service, and keep up-to-date with current marketplace trends." http://www.ehnac.org/files/Criteria/Criteria_2012/HIEAP_Criteria_V1.1_MODULES.pdf
Actors and Associated Responsibilities	

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Question 8: We solicit feedback on the appropriateness of ONC's role in coordinating the governance mechanism and whether certain responsibilities might be better delegated to, and/or fulfilled by, the private sector.	AHIMA supports the development of a public/private entity which would allow for public engagement. We believe modeling the feedback approach after the National Quality Forum (NQF) and the selection process of quality measures for the Centers for Medicare and Medicaid Services (CMS) quality measurement programs. The ONC HIT Standards and Policy Committees are examples by which a mechanism could be established or serve as a framework to leverage current infrastructures currently established.
The Accreditation Body and Validation Bodies	
Question 9: Would a voluntary validation process be effective for ensuring that entities engaged in facilitating electronic exchange continue to comply with adopted CTEs? If not, what other validation processes could be leveraged for validating conformance with adopted CTEs? If you identify existing processes, please explain the focus of each and its scope.	AHIMA does not support establishing a voluntary validation process; rather we strongly believe this process is mandatory in order to participate with the exchange of health information. We recommend that the Office of the National Coordinator (ONC) consider investigating the EHNAC Health Information Exchange Accreditation Program (HIEAP). In our opinion EHNAC currently has an infrastructure to support a validation process. In addition, we believe the National Institute of Standards and Technology (NIST) is well positioned to provide technical guidance during the validation process. Furthermore, we believe that the American National Standards Institute (ANSI) should be approached for guidance when establishing a validation process. We would also like to recommend modeling the validation process after the Medicare Conditions of Participation (CoP).
Entities Eligible for Validation	

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Question 13: Should there be an eligibility criterion that requires an entity to have a valid purpose (e.g., treatment) for exchanging health information? If so, what would constitute a ''valid'' purpose for exchange?	AHIMA recommends the information contained within an HIE should not be leveraged to verify and determine insurance eligibility.
Question 14: Should there be an eligibility criterion that requires an entity to have prior electronic exchange experience or a certain number of participants it serves?	In order to create an environment where innovation and creativity is encouraged; we recommend creating eligibility criterion that would support new and appropriately qualified entities seeking entry to the health information exchange space. It must also be clearly understood among the participants that by entering this process, this is a "give and take" relationship and not a one sided relationship where information is only exchanged by one party.
Question 16: Should eligibility be limited to entities that are tax-exempt under section 501(c)(3) of the IRC? If yes, please explain why.	No, we disagree with the requirement that NVE eligibility to 501(c)(3) should be limited. Additional models should be considered to allow for maximum flexibility in business model design and the needs of the community. For example a 501 (c)(6) or other for profit entity models may best meet the needs of the community.
Stakeholders	
Question 17: What is the optimum role for stakeholders, including consumers, in governance of the nationwide health information network? What mechanisms would most effectively implement that role?	To ensure collaboration and transparency, consumers must to be engaged HIE participants: such active participation demands a clear understanding of HIE governance. Furthermore, to be active participants consumers must to be both healthcare and technology literate regarding electronic health information exchange. We support the notion that consumers must possess an understanding of how data integrity contributes to the accuracy of this information. AHIMA recommend that ONC

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	consider modeling some of the consumer roles employed by the Health Record Banking initiative, leveraging this model for engaging consumers.
Monitoring and Transparent Oversight	
Question 18: What is the most appropriate monitoring and oversight methods to include as part of the governance mechanism for the nationwide health information network? Why?	AHIMA recommends considering the idea of creating an umbrella organization such as one that ties together the various federal agencies and includes private industry representation. We suggest capitalizing on the existing infrastructure created by the Regional Extension Centers (REC) as they are developed regionally and would be positioned well to provide monitoring and oversight activities.
Question 19: What other approaches might ONC consider for addressing violations of compliance with CTEs?	As this structure is being formulated, AHIMA encourages ONC to leverage relationships of other agencies as we expect violations that will occur will cut across various topic areas that need to be addressed.
Question 21: How long should validation status be effective?	AHIMA believes if no changes are made to the business workflow, process, technical infrastructure, policies or procedures then no revalidation of the NVE status should be required. We do support a process modeled after the ONC EHR Certification program. In addition, should it become necessary to update or modify certification standards; then it would be necessary to conduct a re-certification.
Conditions for Trusted Exchange (CTE) – Safeguards CTEs	
Question 22: Are there HIPAA Security Rule implementation specifications that should not be required of entities that	To ensure consistency with HIPAA requirements, AHIMA recommends participants follow the HIPAA Privacy and Security provisions no matter what model is being leveraged.

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facilitate electronic exchange? If so, which ones and why?	
Question 24: What is the most appropriate level of assurance that an NVE should look to achieve in directly authenticating and authorizing a party for which it facilitates electronic exchange?	AHIMA recommends at a minimum, Level 3 authentication. According to the National Institute of Standards and Technology (NIST), Special Publication 800-63 Version 1.0.2, Electronic Authentication Guideline, "Level 3 provides multi-factor remote network authentication. At this level, identity proofing procedures require verification of identifying materials and information. Level 3 authentication is based on proof of possession of a key or a one-time password through a cryptographic protocol. Level 3 authentication requires cryptographic strength mechanisms that protect the primary authentication token (secret key, private key or one-time password) against compromise by the protocol threats including: eavesdropper, replay, on-line guessing, verifier impersonation and man-in-the-middle attacks. A minimum of two authentication factors is required. Three kinds of tokens may be used: 1. "soft" cryptographic tokens, 2. "hard" cryptographic tokens and 3. "one-time password" device tokens."
Question 25: Would an indirect approach to satisfy this CTE reduce the potential trust that an NVE could provide? More specifically, should we consider proposing specific requirements that would need to be met in order for indirect authentication and authorization processes to be implemented consistently across NVEs?	AHIMA recommends the CTE leverage the Public Key Infrastructure (PKI) model that employs a 3rd party Certificate Authority (CA). In addition we recommend providing specific requirements that would need to be met in order for indirect authentication and authorization processes to be implemented. We believe there should be controls to notarize applicants who will be managing access and assigning digital certificate in an indirect approach. The assignment of digital certificates must include a process by which the organization submits a notarized identification for the digital certificate. We do not believe an email digital certificate

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	loaded on a device is sufficient. We would support a third party, Public Key Infrastructure (PKI) model. In our opinion third party oversight would ensure the appropriate level of compliance.
Question 26: With respect to this CTE as well as others (particularly the Safeguards CTEs), should we consider applying the ''flow down'' concept in more cases? That is, should we impose requirements on NVEs to enforce upon the parties for which they facilitate electronic exchange, to ensure greater consistency and/or compliance with the requirements specified in some CTEs?	AHIMA believes that given the two options of direct or indirect authentication and authorization; the best option would be for the NVE to directly authenticate and authorize the parties for which it facilitates exchange. However, if indirect authentication and authorization is the only available option, then it would be critical for the NVE to ''flow down'' these responsibilities and obtain reasonable assurance from the party(ies) for which it facilitates exchange that only authenticated and authorized personnel are able to access electronic exchange services it facilitates where audits are available.
Question 27: In accommodating various meaningful choice approaches (e.g., opt-in, opt-out, or some combination of the two), what would be the operational challenges for each approach? What types of criteria could we use for validating meaningful choice under each approach? Considering some States have already established certain ''choice'' policies, how could we ensure consistency in implementing this CTE?	AHIMA believes ONC should ensuring training and awareness of the policies is conducted for each approach. Over time there should be allowance for patients to address the opt-in, opt-out approaches and allow for enough time to implement this process. It will be critical to ensure consistency on how this policy is implemented
Question 28: Under what circumstances and in what manner should individual choice be required for other electronic	Circumstances where individual choice is considered/required are those that involve chemical dependency, behavioral health, HIV, and other sensitive circumstances.

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exchange purposes?	AHIMA suggests exploring ways in which there can be a limited data set shared among providers for the sensitive data such as those listed above. For example, leveraging the Continuity of Care Document (CCD) specification model may be a method to share limited data sets.
Question 29: Should an additional ‘‘meaningful choice’’ Safeguards CTE be considered to address electronic exchange scenarios (e.g., distributed query) that do not take place following Interoperability CTE I–1?	Meaningful choice is a highly subjective issue and state laws will be critical in defining these constructs. A number of complex underlying issues must first be addressed. As a result it may be better to consider each of the topic areas separately. 1. Individual Choice: Under what circumstances should an NVE give a patient the choice between opt-in and opt-out? 2. Meaningful Choice: Under what circumstances should an electronic health information exchange provide individuals with meaningful choice regarding the exchange of their IIHI? 3. Need to clearly define prohibitive communication; i.e. a provider's boilerplate form or reliance on the patient to read material posted on a provider's waiting room wall or website. 4. Revocability of consent at any time; clear guidelines and processes must be defined. 5. Guidelines and processes that limit the duration of consent authorizations must be established. 6. Granularity of consent: Consensus on policies and technical approaches that offer individuals more granular choice must be defined.
Question 37: What impact, if any, would this CTE have on various evolving business models? Would the additional trust gained from this CTE outweigh the potential impact on these models?	If the NVE chose to disclose de-identified health information, a unique business associate agreement would need to be in place limiting the use of the de-indentified data. To ensure appropriate application, we recommend the de-identification process be established as a standardized process. Before, implementing this CTE, further empirical research regarding the probability of being able to re-identify de-identified data.

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	The NVE should balance the benefits of improved health care quality against the risks of re-identification. We would like to know what studies exist regarding the actual risk of re-identification. What safeguards are available to prevent re-identification? We believe that each contract that involves the sharing of de-identified data should require prior approval of the governing committee of the HIE and the full board approval of the overarching company. Further, the monies made by the business model would be applied to the reduction in participating membership fees.
Question 38: On what other entities would this have an effect?	Medical researchers would be negatively affected. Physicians would be at a disadvantage because the knowledge base from de-identified data would not be available for the establishment of cohort study and disease state baselines. Public health oversight would also be negatively affected; public health entities wouldn't be able to pull information/data for health care outcomes.
Question 41: If an NVE were to honor an individual's request for a correction to the unique set of IIHI that it maintains, what impact could such a correction have if the corrected information was accessible by health care providers and not used solely for the NVE's own business processes?	AHIMA recommends information shared with HIE stakeholders would need to be updated to reflect correction and amendment requested and implemented. Data stewardship guidelines require that changes be made in the source system and all recipients impacted be affectively notified. For additional background on amendment and correction the following AHIMA resources have been provided.[iv]
Question 42: Are there any circumstances where an NVE should not be required to provide individuals with the ability to correct their IIHI?	AHIMA recommends that a process be established for reviewing all requests to append or amend the original health record and safeguards should be in place to prevent falsification of the record. We believe that if the NVE did not author the original record, the NVE would need to refer the patient to the author of the original record. We recommend following the HL7 EHR Records Management and Evidentiary Support Functional Profile (RM-ES FP) which provides functions in an EHR system that can help an organization maintain a legal record for business and disclosure purposes, help

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	reduce a provider's administrative burden, and reduce costs and inefficiencies caused by redundant paper and electronic record keeping.
Question 43: What method or methods would be least burdensome but still appropriate for verifying a treatment relationship?	AHIMA recommends performing audits for the presence of a signed consent or existence of a medical emergency that would verify the treatment relationship. One validation approach could involve using integration tools to conduct a patient-provider match whereby any audit flag would require validation of the treatment relationship.
Question 44: Are there circumstances where a provider should be allowed access through the NVE to the health information of one or more individuals with whom it does not have a treatment relationship for the purpose of treating one of its patients?	AHIMA believes that all circumstances must adhere to all applicable jurisdictional law. Particular instances that would allow providers who do not have a treatment relationship access through the NVE could include the need for public health and law enforcement entities to gain immediate information on infectious disease out-breaks or investigations, exposed or contagious individuals, conditions of individuals where law enforcement are in "hot pursuit", or information necessitated by natural or man-made disaster.
Conditions for Trusted Exchange (CTE) – Interoperability CTEs	
Question 49: Should we adopt a CTE that requires NVEs to employ matching algorithms that meet a specific accuracy level or a CTE that limits false positives to certain minimum ratio? What should the required levels be?	We concur with the recommendations of the Patient Matching Power Team that call for specificity of 99.9% and sensitivity of 95%. In addition, HIEs should have comparable requirements to maintain similar degrees of accuracy in their EMPI. For example, if a discrepancy (such as a name change) is present in an existing record it would be inaccessible using a 95% sensitivity level. We suggest that HIEs have mechanisms in place to require a minimum of 1.0% EMPI accuracy (whereas .5% has been shown to be achievable).
Question 50: What core data elements should be included for patient matching queries?	Regarding the August 17, 2011 HIT Policy Committee recommendation to the HIT Standards Committee where potential matching attributes includes the last 4 digits of the SSN (Table 1 – Potential patient matching attributes under "Other Attributes"). We ask

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	that consideration be given to situations where the SSN is not available or inappropriate to use as an identifier. In these situations, we believe that an alternate unique identifier be assigned. In addition, we believe that when the last four digits of the SSN are used for matching, the numbers should never be displayed as outlined on Table 6-1 Summary of HIO Matching Approaches in the June 30, 2009 "Privacy and Security Solutions for Interoperable Health Information Exchange" white paper. In addition, we would like to point out sections 5.3 on Biometrics and 5.4 on Algorithmic Matching Approaches in the white paper. However, there should be consideration for a national patient data matching strategy. We would also like to suggest the following AHIMA resource: AHIMA. "Fundamentals for Building a Master Patient Index/Enterprise Master Patient Index (Updated). Appendix A: Recommended Core Data Elements for EMPIs." Journal of AHIMA (Updated September 2010).
Question 51: What standards should we consider for patient matching queries?	Further clarification is needed to respond appropriately to this question. For example, how are queries structured and how standards are applied? Are there performance standards that these should be capable to attaining? We recommend there should be a minimal standard of competency in this area. Benchmarking methodology or testing might be helpful to the industry for evaluation of the patient matching technology and algorithm techniques. Effectiveness of the system(s) itself and providing a common means of evaluation would be beneficial to the participants so they are aware of the expectations.
Conditions for Trusted Exchange (CTE) – Business Practice CTEs	
Question 52: Should this CTE be limited	AHIMA supports the establishment of a broader set of limitations and look beyond the

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to only preventing one NVE from imposing a financial precondition on another NVE (such as fees), or should it be broader to cover other instances in which an NVE could create an inequitable electronic exchange environment?	financial barriers possibly created.
Question 54: Under what circumstances, if any, should an NVE be permitted to impose requirements on other NVEs?	To ensure data integrity and accuracy of health information, AHIMA provides some examples of the necessity for data integrity and they are included in the following resources: Managing the Integrity of Patient Identity in Health Information Exchange AHIMA e-HIM Workgroup on HIM in Health Information Exchange. "HIM Principles in Health Information Exchange." Journal of AHIMA 78, no.8 (September 2007):
CTE Processes and Standards and Implementation Specification Classification – CTE Life Cycle	
Question 60: What process should we use to update CTEs?	AHIMA recommends to the extent possible; make use of existing organizational structures and frameworks that have been established. For example EHNAC, ONC's Authorized Testing and Certification Bodies (ATCB) have a process by policies and procedures are updated within their accreditation methodologies. We believe CTEs should follow a life-cycle model and it is important to have a process by which CTEs are systematically reviewed.

We thank you for the opportunity to provide comments on the Nationwide Health Information Network request for information and if AHIMA can provide additional information, or if there are any questions or concerns regarding this letter, please contact Allison Viola, senior director, federal relations allison.viola@ahima.org (202) 659-9440 or AHIMA's vice president, advocacy and policy, Dan Rode, at (202) 659-9440 or dan.rode@ahima.org. If we can be of further assistance to you in your efforts, we would welcome the opportunity to provide support.

Sincerely,

Lynne Thomas Gordon, MBA, RHIA
Chief Executive Officer

cc: Dan Rode, MBA, CHPS, FHFMA
Harry B. Rhodes, MBA, RHIA, CHPS, CPHIMS, FAHIMA

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[i] KLAS Research, Orem, UT. (Health Information Exchanges: Rapid Growth in an Evolving Market,) June 2011.
[ii] eHealth Initiative, Washington, DC. (2011 Report of Health Information Exchange: Sustainable HIE in a Changing Landscape,) 2011.
[iii] Dimick, Chris. "Open for Business: Private Networks Create a Marketplace for Health Information Exchange." *Journal of AHIMA* 83, no.5 (May 2012): 22-26.
[iv] "Patient Access and Amendment to Health Records (Updated)." (Updated January 2011). http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_048587.hcsp?dDocName=bok1_048587
AHIMA "Amendments, Corrections, and Deletions in the Electronic Health Record Toolkit. August 24, 2009. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_044678.hcsp?dDocName=bok1_044678